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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,910	06/29/2000	Uwe Karsten	0107-027P	7839

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/606,910	KARSTEN ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-13 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-13 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice of Non-Compliant Amendment.

DETAILED ACTION

1. The amendment filed November 30, 2004 is acknowledged and has been entered. Claims 19-24 have been canceled. Claims 8-13 and 15-18 have been amended.

2. Claims 8-13 and 15-18 are pending in the application and are currently under prosecution.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following Office action contains NEW GROUNDS of rejection necessitated by amendment.

Priority

5. Applicant's submission of a certified translation of the German foreign priority document 197 98 400.4 (30 December 1997) is acknowledge and has been entered.

6. Applicant's claim under 35 USC § 120 for benefit of the earlier filing date of PCT Application No. PCT/DE98/03819, filed December 30, 1998, which claims benefit of the German priority document 197 98 400.4 (30 December 1997), is acknowledged.

However, claims 8-13 and 15-18 do not properly benefit under 35 U.S.C. § 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description; see the "new matter' rejection of those claims set forth below.

To receive benefit of the earlier filing date under 35 USC §120, the later-filed application must be an application for a patent for an invention which is also

disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Accordingly, the effective filing date of the claims is deemed the filing date of the instant application, namely June 29, 2000.

Grounds of Objection and Rejection Withdrawn

7. Unless specifically reiterated below, Applicant's amendment filed August 4, 2005 and/or the accompanying arguments have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed March 3, 2005.

Grounds of Objection and Rejection Maintained

Specification

8. As noted on the attached Notice of Non-Compliant Amendment, the amendment filed August 4, 2005 fails to meet the requirements of 37 C.F.R. § 1.121.

Until the a corrected amendment providing a compliant "Amendments to the Specification" section is provided, the disclosure is objected to for the reasons set forth in section 9 of the preceding Office action.

Claim Rejections – 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The rejection of claims 8 and 10-13 under 35 U.S.C § 102(b), as being anticipated by Karsten et al. (*Cancer Res.* 1998 Jun 15; **58** (12): 2541-2549), is maintained.

At page 18 of the amendment filed august 4, 2005 Applicant has traversed this ground of rejection.

Applicant's argument has been carefully considered but not found persuasive for the following reasons:

As explained in the prior Office action, Karsten et al. teaches "MUC1 tandem repeat peptides", which comprise SEQ ID NO: 3 and are glycosylated at the threonine residue of SEQ ID NO: 3; see entire document (e.g., page 2542, Table 2). The peptides (e.g., peptides "A1" and "A12") are either α-N-acetylgalactosamine (GalNAc)- or Galβ1-3GalNAc-glycosylated at the threonine residue of SEQ ID NO: 3; see page 2542, Table 2. GalNAc is a monosaccharide; and Galβ1-3GalNAc is a disaccharide (i.e., an oligosaccharide).

At page 18 of the amendment filed August 4, 2005 Applicant has traversed this ground of rejection, arguing it has been obviated by Applicant's submission of the certified translation of the German foreign priority document 197 98 400.4 (30 December 1997). Applicant's argument has been carefully considered but not found persuasive because the present claims do not properly benefit from the earlier filing dates of the priority documents, since, as further explained below in the "new matter" rejection, the specification, including the claims, as originally filed, do not provide proper and sufficient written support for the present claims.

New Ground of Objection

Claim Objections

11. Claims 8 and 10-13 are objected to because claim 1 recites, "consisting of 7-21 contiguous amino acids of the sequence AHGVTSAPDTRPAPGSTAPPA of SEQ ID NO: 1". The sequence recited in claim 1 is the sequence identified as SEQ ID NO: 1; yet, the recitation would suggest that the sequence is a mere part of the sequence identified as SEQ ID NO: 1. Accordingly, claim 1 should instead recite, for example, "consisting of 7-21 contiguous amino acids of the sequence AHGVTSAPDTRPAPGSTAPPA (SEQ ID NO: 1)". Appropriate correction is required.

12. Claim 9 is objected to because it recites, "wherein each of said tandem repeats comprises the sequence PDTRAP (SEQ ID NO: 3) glycosylated at the threonine residue". Claim 9 depends from claim 8, which recites, "wherein sequence PDTRPAP (SEQ ID NO: 3) is glycosylated at the threonine residue". Accordingly, because claim 9 is drawn to a synthetic peptides consisting of at least two tandem repeats consisting of the amino acid sequence of the peptide of claim 8, the recitation of this limitation in claim 9 is redundant. Appropriate correction is required.

New Grounds of Rejection

13. Claims 8-13 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "new matter" rejection.

Claims 8 and 10-13 are directed to a genus of synthetic peptides "consisting of 7-21 contiguous amino acids of the sequence" set forth as SEQ ID NO: 1.

Claims 9 and 15-18 are directed to a genus of synthetic peptides that consist of "at least two tandem repeats" of the amino acid sequence of a peptide according to claim 8.

At page 12 of the amendment filed August 4, 2005 Applicant has asserted that support for the amendment is found throughout the specification, including the claims, as originally filed, and particularly in the final full paragraph of claim 2, the first full paragraph of page 3, and in the table on page 5.

Applicant's assertions has been carefully considered but to the contrary the specification, including the claims, as originally filed, does not appear to provide proper and sufficient written support for the language of the present claims.

Firstly, it is noted that the original claims were written in German; although a translation of the originally filed claims has not been provided, it does not appear that these claims, and particularly claim 2 provide written support for a peptide consisting of 7-21 contiguous amino acids of SEQ ID NO: 1; nor does it appear that these disclosure provide written support for claims directed to a genus of synthetic peptides that consist of "at least two tandem repeats" of the amino acid sequence of a peptide according to claim 8. Instead, it appears that original claim 2 would provide support for a peptide that is at least 20 amino acids, or between 40-120 amino acids in length.

The first full paragraph on page 3 describes synthetic peptide having varying lengths but comprising the amino acid sequence set forth as SEQ ID NO: 3, which suitably comprise at least 20 amino acids. This disclosure, however, does not provide written support for a peptide consisting of 7-21 contiguous amino acids of SEQ ID NO: 1; nor does it appear to provide support for synthetic peptides that consist of multiple repeats of such peptides, as recited in claim 9.

The table on page 5 describes peptides which are either 20 or 21 amino acids in length, which comprise the amino acid sequences set forth as SEQ ID NO: 2 and SEQ ID NO: 1, respectively. However, this disclosure also does not provide written support for a peptide consisting of 7-21 contiguous amino acids of

SEQ ID NO: 1; nor does it appear to provide support for synthetic peptides that consist of multiple repeats of such peptides, as recited in claim 9.

Accordingly, the recitations of the limitations in claims 8 and 9 appear to introduce new matter and thereby violate the written description requirement set forth under 35 U.S.C. § 112, first paragraph.

This issue might be resolved if Applicant were to point elsewhere to other specific disclosures in the specification, including the claims, as originally filed, which are believed to provide the necessary written support.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 9 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karsten et al. (*Cancer Res.* 1998 Jun 15; **58** (12): 2541-2549).

Karsten et al. teaches that which is set forth above in the rejection of claims 8 and 10-13 under 35 U.S.C. § 102(b).

In addition, Karsten et al. teaches, "[a]nother question to be answered by further studies is whether both factors (length of the peptide and DTR glycosylation) might act synergistically with respect to their influence upon the immunogenicity of MUC1 peptides" (page 2549, column 1). Karsten et al. teaches synthetic peptide oligomers consisting of three, five, or six repeats of MUC1 tandem repeat domain; see, e.g., page 2542, column 2. Karsten et al. shows comparisons between these oligomers and either the glycosylated or non-glycosylated peptide monomer consisting of the amino acid sequence of a single MUC1 tandem repeat domain; see, e.g., page 2544, column 2. In general, the glycosylated monomer showed more activity than the oligomer, which, in turn, showed more activity than the non-glycosylated monomer; see, e.g., page 2544,

column 2. However, Karsten et al. also shows that in most instances, the longer the length of the oligomers the greater the activity; see, e.g., page 2543, Table 4. It is for this reason that Karsten et al. suggests the aforementioned further studies to address the effects of both length and glycosylation.

Accordingly, it would have been *prima facie* obvious to one ordinarily skilled in the art at the time of the invention to synthesize peptides consisting of at least two repeats of the amino acid sequence of the peptide monomers, which are glycosylated at the threonine in the same manner as the peptide monomer, so as to permit one to determine the effects of both length and glycoylation, since Karsten et al. suggest such further study be performed to determine if these factors might act synergistically with respect to their influence upon the immunogenicity of MUC1 peptides. One ordinarily skilled in the art at the time of the invention, therefore, would have been motivated to do so permit one to perform the further studies needed to determine if both factors (length of the peptide and DTR glycosylation) might act synergistically with respect to their influence upon the immunogenicity of MUC1 peptides.

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
October 17, 2005

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No.	Applicant(s)	
	09/606,910	KARSTEN ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on *04 August 2005* is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☒ 1. Amendments to the specification:
  - ☒ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☒ C. Other *See Continuation Sheet*.
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other _____.
- ☐ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☐ E. Other: _____.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf .

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.

2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

   Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

   Failure to timely respond to this notice will result in:
   Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
   Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Continuation of 1(c) Other: While it is noted that Applicant has provided a marked up version of the amended paragraphs, it is currently not the practice to provide such a marked up version, as the amended paragraphs are themselves marked to show changes relative to the immediate prior versions..